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Michaela Hagermark

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EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,963	Applicant(s) HAGERMARK ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9 and 12-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9 and 12-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,364,385 to Harms et al in view of US 4,396,382 to Goldhaber, further in view of US 4,731,072 to Aid.

In the specification and figures, Harms discloses the apparatus substantially as claimed by Applicant. With regard to claims 1-5, Harms discloses a fluid bag 10 with a single compartment defined by a plurality of edges (attachment areas 40) that contains a fluid therein. The bag is made of flexible sheets, 11, 12 that are sealed along their periphery (see at least column 5, lines 30-40) and is configured to never exceed a certain thickness or depth when hung (see column 6, lines 61-68).

It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP § 2144.05(II)(A). It is the position of the Examiner that Harms discloses the general conditions of the claim (that is, a flexible-sheet fluid bag with a compartment wherein the bag is configured remain at a predetermined thickness when filled). As such, it is within the skill of a worker in the art to configure the bag to

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maintain a preferred volume-to-thickness ratio, since such a configuration may be obtained via routine experimentation.

With regard to the contents of the bag, Harms discloses that the bag contains blood products, not dialysis fluids as claimed by Applicant. However, Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bag disclosed by Harms to contain the dialysis fluids as disclosed by Goldhaber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to Applicant's recitation that the distance limiting members extend to the boundaries of the sheets, neither Harms nor Goldhaber illustrate such an arrangement. However, Aid discloses a bag for heating or cooling fluids that comprises lines of attachment made by heat sealing (see FIG 2, column 8, lines 36-55), wherein some of the lines (235, 144, 150) extend to the boundary of the container, creating secondary flow channels. Aid discloses that additional "lines of attachment" such as 150 may be placed within the bag to create additional secondary flow channels. Such additional "lines of attachment" may be adjacent one another (see column 10, lines 15-40). The lines may serve to limit the liquid holding capacity of the bag. It has been held that where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under

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35 U.S.C. 103(a). Ex Parte Smith, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing KSR v. Teleflex, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). In the instant case, expansion limiting members that extend to the boundary of a container are known in the art. Furthermore, Applicant has submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

With regard to claims 8-9 and 12, Harms discloses that the thickness or expansion of bag 10 is limited by a plurality of straight seal lines 60 (see column 6, lines 61-68).

With regard to claims 13-14, Goldhaber discloses that the bag comprises two compartments, allowing a single bag to be used for both fresh and spent dialysis fluid (see column 1, lines 35-40). Furthermore, it is the position of the Examiner that the mere duplication of the compartments found in the bag disclosed by Harms, without any new and unexpected results, is within the skill of a worker in the art. See MPEP § 2144.04 (VI)(B). As such, it is the position of the Examiner that the cited prior art suggests a multi-chambered fluid bag in order to simplify bag use with distance limiting members such as those taught by Harms in order to limit the thickness of the filled bag.

With regard to claims 15-16, Harms discloses an attachment member (hole 18 in edge 16) that allows the bag to be held in a suspended position (see FIG 1).

With regard to claims 17, 27, 28, and 38, Goldhaber discloses that the bag may be connected via conduit 34 to catheter 36 for peritoneal dialysis (see FIG 1 and accompanying text).

With regard to claims 18-19, 25, 29,30, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, both the Harms and Goldhaber bags are configured to be suspended by a holding apparatus via holes (see FIG 1 of each of Harms and Goldhaber). The prior art does not specifically cite the presence of a holding member, but reasonably suggests such a member, thereby suggesting the limitations of the claims (see, specifically, Harms, column 10-12, Goldhaber, column 5, lines 56-60).

With regard to claims 20-24, 26, 31,-37, it has been held that the mere duplication of the parts of an apparatus found in the prior art (such as the bags and holding means suggested in the combinations proposed above) is not patentably significant unless a new and unexpected result is produced. See MPEP § 2144.04 (VI)(B). Furthermore, the placement of the bags as recited in claims 22-24 and 32-34 is a statement of the intended use of the claimed invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the bags suggested by the prior art are capable of

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being suspended in the arrangement claimed by Applicant, suggesting the limitations of the claims.

With regard to claim 39, the cited prior art suggests a bag with multiple compartments (Goldhaber) with distance limiting members (Harms) wherein the distance limiting members are formed at a location between the edges of the bag (Harms).

With regard to claim 41, Goldhaber illustrates that the compartments may be separated from one another by edge weld at 18 between the first main sheet 12 and second main sheet 16 (see FIG 2).

3. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2080116A to Matthews in view of US 4,396,382 to Goldhaber, further in view of US 4,731,072 to Aid.

In the specification and figures, Matthews discloses the apparatus substantially as claimed by Applicant. With regard to claims 1-5, Matthews discloses a fluid bag with a compartment that contains a fluid therein. The bag is made of flexible sheets, 10, 12 that are sealed along their periphery (see specification) and is configured to never exceed a certain thickness or depth when hung.

It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP § 2144.05(II)(A). It is the position of the Examiner that Matthews discloses the general conditions of the claim (that is, a flexible-sheet fluid bag

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with a compartment wherein the bag is configured remain at a predetermined thickness when filled). As such, it is within the skill of a worker in the art to configure the bag to maintain a preferred volume-to-thickness ratio, since such a configuration may be obtained via routine experimentation.

With regard to the contents of the bag, Matthews discloses that the bag contains waste products, not dialysis fluids as claimed by Applicant. However, Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bag disclosed by Matthews to contain the dialysis fluids as disclosed by Goldhaber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to Applicant's recitation that the distance limiting members extend to the boundaries of the sheets, neither Matthews nor Goldhaber illustrate such an arrangement. However, Aid discloses a bag for heating or cooling fluids that comprises lines of attachment made by heat sealing (see FIG 2, column 8, lines 36-55), wherein some of the lines (235, 144, 150) extend to the boundary of the container, creating secondary flow channels. Aid discloses that additional "lines of attachment" such as 150 may be placed within the bag to create additional secondary flow channels. Such additional "lines of attachment" may be adjacent one another (see column 10, lines 15-40). The lines may serve to limit the liquid holding capacity of the bag. It has been held that where a claimed improvement on a device or apparatus is no more than "the simple

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substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). In the instant case, expansion limiting members that extend to the boundary of a container are known in the art. Furthermore, Applicant has submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

With regard to claims 8 and 12, Matthews discloses that the thickness or expansion of bag is limited by a plurality of looped welded members 20 (see FIG 1).

With regard to claims 13-14, Goldhaber discloses that the bag comprises two compartments, allowing a single bag to be used for both fresh and spent dialysis fluid (see column 1, lines 35-40). Furthermore, it is the position of the Examiner that the mere duplication of the compartments found in the bag disclosed by Matthews, without any new and unexpected results, is within the skill of a worker in the art. See MPEP § 2144.04 (VI)(B). As such, it is the position of the Examiner that the cited prior art suggests a multi-chambered fluid bag in order to simplify bag use with distance limiting members such as those taught by Matthews in order to limit the thickness of the filled bag.

With regard to claims 15-16, Goldhaber discloses an attachment member (unlabeled hole in top edge 18, see FIG 1) that allows the bag to be held in a suspended position.

With regard to claims 17, 27, 28, and 38, Goldhaber discloses that the bag may be connected via conduit 34 to catheter 36 for peritoneal dialysis (see FIG 1 and accompanying text).

With regard to claims 18-19, 25, 29, 30, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the Goldhaber bag is configured to be suspended by a holding apparatus via holes (see FIG 1 of Goldhaber). The prior art does not specifically cite the presence of a holding member, but reasonably suggests such a member (see, specifically, Goldhaber, column 5, lines 56-60).

With regard to claims 20-24, 26, 31-37, it has been held that the mere duplication of the parts of an apparatus found in the prior art (such as the bags and holding means suggested in the combinations proposed above) is not patentably significant unless a new and unexpected result is produced. See MPEP § 2144.04 (VI)(B). Furthermore, the placement of the bags as recited in claims 22-24 and 32-34, is a statement of the intended use of the claimed invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed

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structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the bags suggested by the prior art are capable of being suspended in the arrangement claimed by Applicant, suggesting the limitations of the claims.

With regard to claim 39, the cited prior art suggests a bag with multiple compartments (Goldhaber) with distance limiting members (Matthews) wherein the distance limiting members are formed at a location between the edges of the bag (Matthews).

With regard to claim 41, Goldhaber illustrates that the compartments may be separated from one another by edge weld at 18 between the first main sheet 12 and second main sheet 16 (see FIG 2).

Response to Arguments

4. Applicant's arguments, filed 13 January 2011, with respect to the pending claims have been fully considered but are not persuasive.
5. Applicant argues that Aid fails to disclose that "adjacent" distance limiting members meet a common edge of the one or more compartments. Applicant has not defined "adjacent" in the specification. As such, it is given its broadest reasonable interpretation. Merriam-Webster defines "adjacent" as "not distant, nearby." (Merriam-Webster Collegiate Dictionary, 10th Edition, 2001.) It is the position of the Examiner that "lines of attachment" 135 and 150 are nearby one another. If more "lines of attachment" are added, as per the disclosure in column 10, those may similarly be located nearby the existing lines of attachment. The instantly claimed invention is not patentable over the prior art.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 February 2011